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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,923	11/25/2003	Janet Codd	102458-40933 (Nascime 2)	8326

996 7590 07/25/2006

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,923	CODD ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 15, 2006 has been entered.

Action Summary

The rejection of claims 12-21 under 35 U.S.C. 103(a) as being unpatentable over Media Release (November 4, 2002) in view of Hirsh et al. (US 2003/0035839 A1) is being maintained for the reasons stated in the previous office action.

Response to Arguments

Applicants' arguments filed May 15, 2006 have been fully considered but they are not persuasive. Applicants argue that there is no disclosure or suggestion in the reference of the two compartment oral unit dosage form of the present invention in

Media Release reference. This is not persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the active agent, ocinaplon, is well known to be formulated in controlled-release oral formulation by Media Release reference and Hirsh et al. teach the formulation of anxiolytic in two different portions having same active agent in both portions in delayed release is old and well known. Therefore, it would have been obvious to one of ordinary skill in the art to modify the controlled-release ocinaplon of Media Release formulated in any known formulation of anxiolytic including two different portions in a delayed release formulation well-known by Hirsh et al. without a surprising and unexpected result. Applicants argue that the second reference, Hirsh et al. is deficient because there is no disclosure in Hirsh et al. of a two compartment oral unit dosage form of the present invention and the present invention is utilized only for oral **ingestion**. This is not persuasive because Hirsh et al. teach new pharmaceutical composition in unit dosage form comprising anxiolytic in two different portions comprising immediate (outer layer) as well as sustained release (core) in both intraoral and oral administration. (page 14, claim 29). Applicants' intended utility for "oral **ingestion**" not represent a patentable limitation since such fails to impart any physical limitation to the composition. Applicants argues that Hirsh et al. actually teaches away

from the subject matter of the current invention because all of the working examples provided by Hirsh et al. of a "two portion" (outer layer and inner core) dosage forms are comprised of two separate drugs, which are each delivered in a separate phase of a distinct, bi-phasic delivery modality. This is not persuasive because that Hirsh et al. selected the working example provided by dosage forms comprising two separate drugs does not "teach away" from using the same drug in two separate phase because Hirsh et al. clearly states that the active ingredient of the composition may be the same pharmaceutically active ingredient. [0014]. There remains, even after the Hirsh et al. disclosure, a reasonable expectation of success that same pharmaceutical active ingredient in two separate compartments taught by Hirsh et al., each containing same anxiolytic (ocinaplon) would work, as long as one were willing to use same active agent for selection as taught by Hirsh et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above, the Office Action of 1/11/2006 is deemed proper and asserted with full force and effect herein to obviate applicants' claims. The rejections are restated below for the Applicants' convenience.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in prior Office Action.

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Media Release (November 4, 2002) in view of Hirsh et al. (US 2003/0035839 A1).

Media Release announces positive phase II results for ocinaplon as a novel anti-anxiety product in its therapeutic use for generalized anxiety disorders. (title). Media Release teaches that ocinaplon is a non-benzodiazepine that exhibits anxiolytic-like effects in animal studies as a similar pharmacological profile to anxiolytic benzodiazepines. Media Release teaches controlled-release ocinaplon administered twice or three times a day is effective in the treatment of patients with generalized anxiety disorders. Media Release teaches ocinaplon was administered orally 60mg three times a day or 120mg twice a day for 14 days. (Content).

Media Release does not teach the two separate compartments each containing ocinaplon with specific amounts with rapid release in first compartment and sustained release in second compartment with hydrophilic polymeric matrix (hydroxypropyl methyl cellulose) in a unit dose, carriers such as lactose and a particle size.

Hirsh et al. teach new pharmaceutical composition in unit dosage form comprising anxiolytic in two different portions comprising immediate (outer layer) as well as sustained release (core). (abstract, [0012], [0014], [0028], [0038]-[0042]). Hirsh et al. teach that the inner core of the composition can be formulated as a delayed release coating with hydroxypropyl methylcellulose. ([0060]. Hirsh et al. teach that the core of the composition can be formulated with inert carrier such as lactose. ([0031]). Hirsh et

al. teach that the active ingredient of the composition may be the same pharmaceutically active ingredient. ([0014]). Hirsh et al. teach that the composition provides immediate as well as sustained and prolonged therapeutic benefit and improves compliance. ([0016]-[0012]).

It would have been obvious to one of ordinary skill in the art to modify the controlled-release ocinaplon of Media Release to the composition in unit dosage form comprising two portions as taught by Hirsh et al. One would have been motivated to make such a modification in order to achieve the advantage of two portion comprising immediate as well as sustained release to improve prolonged therapeutic benefit and improve the compliance as taught by Hirsh et al. It would have been obvious to one of ordinary skill in the art to employ hydroxypropyl methyl cellulose in delayed release coating since Hirsch et al teaches that the hydroxypropyl methyl cellulose is useful in delayed release portion as a coating. One would have been motivated to make such a modification with a reasonable expectation of successfully coating delayed portion with hydroxypropyl methyl cellulose as taught by Hirsch et al. The amounts of active agent (ocinaplon) to be used in each portion, the pharmaceutical carriers (e.g. lactose), and the particle size are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and each portion can be formulated with same active agent contained therein and the utilization of lactose as a carrier is well taught by Hirsch et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

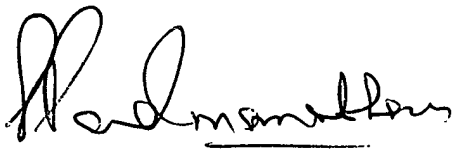
All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

July 14, 2006
jmk